



UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 97,150-C)

PATENT

In the Application of:)
Fruehauf) Group Art Unit:1642
Serial No. 09/982,286) Examiner: J. Burke
Filing Date October 16, 2001)
For: Methods for Cancer Prognosis and)
Diagnosis)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

TECH CENTER 1600/2900

MAY 16 2002

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Dear Sir:

Pursuant to 37 C.F.R. Sections 1.97 - 1.99, the Applicants wish to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56.

Copies of the references cited below are enclosed. These references are also listed on the enclosed PTO Form 1449.

It is requested that the references be given careful consideration and that they be cited of record in the present application so that they will appear on the face of the patent issuing from the present application. Return of an initialed PTO-1449 indicating the Examiner's consideration of the references is requested.

In the judgment of the undersigned, portions of the references may be material to the examination of the pending claims. However, the references have not been reviewed in sufficient detail to make any other representation and, in particular, no representation is intended as to the relative importance of any portion of the references. This Statement is not a representation that the cited references have effective dates early enough to be "prior art" within

the meaning of 35 U.S.C. Sections 102 or 103. This Information Disclosure Statement shall not be construed as an admission that the statement or cited references are, or are considered to be, material to patentability. 37 C.F.R. Section 1.97(h).

U.S. Patents

Fruehauf U.S. Patent Number 6,303,324 Issued 10-16-2001

Cited References

SALVESAN et al., "Significance of Tumour-Associated Macrophages, Vascular Endothelial Growth Factor and Thrombospondin-1 Expression for Tumour Angiogenesis and Prognosis in Endometrial Carcinomas", Int. J. Cancer", 1999, 84:539-543.

HEDGE et al., "Tumor Angiogenesis and p53 Mutations", Arch Otolaryngol Head Neck Surg, Jan 1998, 124:80-85.

OSHIKA et al., "Thrombospondin 2 Gene Expression Is Correlated with Decreased Vascularity in Non-Small Cell Lung Cancer!", Clin Can Res. Jul. 1988, 4:1785-1788.

BORING et al., "Cancer Stastistics, 1992", CA-A Cancer Journal for Clinicians, January/February 1992, 42:19-38.

MANSOUR et al., "Efficacy of Adjuvant Chemotherapy in High-Risk Node-Negative Breast Cancer", N. Engl. Med., 1989, 320:485-490.

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VON ROSEN et al., "Prognostic Value of Nuclear DNA Content in Breast Cancer in Relation to Tumor Size, Nodal Status, and estrogen receptor content*", Breast Cancer Res. And Treat., 1989, 13:23-32.

FISHER et al., Neoplasms of the Breast", J. Natl. Cancer. Inst., 1992, 1706-1774.

CLARK et al., Prediction of Relapse or Survival in Patients with Node-Negative breast Cancer by DNA Flow Cytometry", New Engl. J. Med., 1994, 320:627-633.

FISHER et al., "Prognostic Factor in NSABP Studies of Women with Node-Negative Breast Cancer", Journal of the National Cancer Institute Monographs, 1992, 11:151-158.

EARLY BREAST CANCER TRIALISTS' COLLABORATION GROUP, "Systemic Treatment of Early Breast Cancer by Hormonal, Cytotoxic, or Immune Therapy", Lancet, 1992, 339:1-15.

THE LUDWIG BREAST CANCER STUDY GROUP, "Prolonged Disease-Free Survival After One Course of Perioperative Adjuvant Chemotherapy for Node-Negative Breast Cancer" N. Engl. Journal of Medicine, vol 320, no. 8 pages 491-496.

GASPARINI et al., "Evaluating the Potential Usefulness of New Prognostic and Predictive Indicators in Node-Negative Breast Cancer Patients", Jour. of the National Cancer Insti. 1993, vol. 85, no. 15 pages 1206-1219.

FIGGE et al., "Image Analysis Quantitaion of Immunoreactive Retinoblastoma Protein in Human Throid Neoplasms with a Streptavidin-biotin-peroxidase Staining Technique" Amer. J. Pathol. 1991, 139:1213-1221.

ESTEBAN et al., "Improvement of the Quantification of Estrogen and Progesterone Receptors in Paraffin-Embedded Tumors by Image Analysis", Amer. J. Clin. Pathol., 1993, 99:32-38.

BEVILACQUA et al., "Prognostic Value of Intratumoral Microvessel Density, a Measure of Tumor Angiogenesis, in node-negative breast carcinoma-results of a multiparametric study", Breast Cancer Research and Treatment, 1995, 36:205-217.

ZABRENETZKY et al., "Expression of the Extracellular Matrix Molecule Thrombospondin Inversely Correlates with Malignant Progression in Melanoma, Lung and Breast Carcinoma Cell Lines", Int. J. Cancer, 1994, 59:191-195.

IWAYA et al., "Nuclear p53 Immunoreaction Associated with Poor Prognosis of Breast Cancer", Jpn. J. Cancer Res., July 1991, 82:835-840.

GASPARINI et al., "Clinical Importance of the Determination of Tumor Angiogenesis in Breast Carcinoma: Much More Than a New Prognostic Tool", Journal of Clinical Oncology, March 1995, vol. 13, No. 3,765-782.

GROSSFELD et al., "Thrombospondin-1 Expression as an Independent Prognostic Indicator in Invasive Transitional Cell Carcinoma of the Bladder", Proceedings of the American Urological Association, May 1996, vol. 155 Supplement 688A Abstract 1508.

Date: May 9, 2002

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff

By:

Kevin E. Noonan
Reg. No. 35,303

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

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 MAY 10 2002
 PATENT & TRADEMARK OFFICE

Application No.	09/982,286
Filing Date:	10/16/2001
First Named Inventor	Fruehauf
Group Art Unit	1642
Examiner Name	J. Burke
Attorney Docket No.	97,150-C

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Figures Appear
		Number	Kind Code ² (if known)			
		6,303,324	B1	Fruehauf	10-16-2001	

FOREIGN PATENT DOCUMENTS

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. 1	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
		SALVESAN et al., "Significance of Tumour-Associated Macrophages, Vascular Endothelial Growth Factor and Thrombospondin-1 Expression for Tumour Angiogenesis and Prognosis in Endometrial Carcinomas", Int. J. Cancer", 1999, 84:539-543.
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Examiner Signature		Date Considered

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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English translation is attached.

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Substitute for form 1449A/PTO



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